

MEDICAL RECORD	CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY • Adult Patient or • Parent, for Minor Patient
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INSTITUTE: National Institute of Child Health and Human Development

STUDY NUMBER: 97-CH-0076 PRINCIPAL INVESTIGATOR: Constantine A. Stratakis, M.D.

STUDY TITLE: Tumors of the Pituitary Gland and Associated Conditions: A Genetic Investigation

Latest IRB Review: Continuing Review 2/4/04

Latest Amendment Approved: Amend D 1/12/03

Consent Form 1 - Linkage Study and Tumor Tissue Collection

INTRODUCTION

We invite you to take part in a research study at the National Institutes of Health (NIH).

First, we want you to know that:

Taking part in NIH research is entirely voluntary.

You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled. However, to receive care at the NIH, you must be taking part in a study or be under evaluation for study participation.

You may receive no benefit from taking part. The research may give us knowledge that may help people in the future.

Second, some people have personal, religious or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). If you have such beliefs, please discuss them with your NIH doctors or research team before you agree to the study.

Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone at NIH, or with family, friends or your personal physician or other health professional.

You, your child or one of your relatives has a tumor in one of the glands of the human body that produce hormones, called the "pituitary gland". The cause of this disease is unknown, but in some cases these tumors are inherited ("run in families"). The purpose of this study is to study the inheritance of these tumors.

In order to do this, we need blood specimens from members of families in which someone has such a tumor. We will use these samples to get DNA. DNA is the substance that contains the genes, the units that determine inheritance. We will compare the DNA from various family members to see if we can find something in common among the people who have the tumor. This will help us and other investigators to find the responsible genes.

The DNA and tumor samples will be stored with codes assigned to them in our laboratory at the NIH. The principal investigator of the study has the key to the code that identifies the patient and links him or her to a particular sample. All these samples will be stored at the NIH and not used for any other studies without your permission. Coded samples may be used by other scientists, who collaborate with the investigators of this study, in the effort to identify the genetic

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defects involved. These investigators will not have access to the names that identify the specimens that are used in these research experiments, without your permission.

You or your child will probably only need to see us or your physician once to complete this study. The parts of the study include:

- (1) Medical history: We will ask you or your child questions concerning symptoms or diseases that have happened to you or your child, such as various tumors or other related diseases. We will also ask you to help us draw a family tree. In few cases, we may ask for additional medical records for certain diseases, and we may need to contact the doctors that took care of you. We will ask you to sign a form to let us see those records.
- (2) Blood drawing: We will draw about 2 tablespoons (30 ml) of blood. We will use this blood to get DNA.

We will tell you and your doctor the results of these DNA tests, if obtained in a manner that is appropriate and certified by the appropriate regulating agencies (in our or other collaborating laboratories). These tests may indicate that you are affected or unaffected by the disease that runs in your family. We will also discuss with you or your child what a "positive" test means; the risk for having a tumor yourself, and the risk for having children with this disease.

Results of genetic (experimental studies) of the tissue derived from the tumor that will be taken out from your child will not be discussed and will not be part of the medical record, unless they have some relationship to your or your child's health. Most of these studies are of interest to the scientists that are doing them and may provide useful information for research and perhaps health care in the future, but they are of no use to current medical care.

If we learn anything else about your or your child's medical condition during the course of this study, we will inform you and your doctor. Although we would be happy to discuss possible treatments of the disease(s) with you, this part of the study does not offer treatment for any conditions. Also, our DNA studies are only of the inheritance of pituitary tumors and related conditions. We will not test for any other genetic condition without your assent and written consent.

If in the process of studying your or your child's DNA we find out that genetic information does not match the family information that you have provided us with (if, in other words, we identify problems with paternity or any other mismatch), we will not reveal this information to you, your child or anywhere else. We will also not use these samples for our research.

By agreeing to participate in this study, you do not waive any rights that you may have regarding access to and disclosure of your records. For further information on those rights please contact the principal investigator (Dr. Stratakis) or your primary and referring physician (if you are being seen at another institution).

If you or your child desire that you, or your child or your doctor should not be informed on the results of our study of DNA, we will respect those wishes.

Risks and Discomfort

1. The time involved in giving information about medical and family history.

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2. The discomfort of blood drawing: this includes the pain of the needle-stick, the slight chance of fainting, the possibility of a bruise, and the small chance of an infection at the needle puncture site. You will receive appropriate treatment for any complications of this sort.

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3. Although we will not reveal the results of our genetic testing to anybody else other than you, your child and your doctor, it is possible that this information can lead to alterations in insurability, which in turn might affect your or your child's ability to find employment.

Benefits

1. We will talk to you or your child about the results of our studies. It is possible that information from these studies will allow us to predict who in your family will develop a pituitary tumor. If we identify this information, we will tell you if you or your child have, or are at risk for, a genetic condition that may lead to the development of such tumors.
2. If you or your child has a genetic condition, or if we discover that you are at risk for developing any of these diseases or their complications, we will discuss with you the chance that your children could have the disease. If it is appropriate, we will arrange that you or your child is seen by a genetic counselor.
3. The knowledge derived from this study may give us a better understanding of pituitary tumors and other conditions associated with them, eventually leading to better treatments and identification of ways of earlier detection or even possible prevention of these tumors.

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OTHER PERTINENT INFORMATION

1. Confidentiality. When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

The Federal Privacy Act protects the confidentiality of your NIH medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or other authorized people.

2. Policy Regarding Research-Related Injuries. The Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the National Institutes of Health, the Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

3. Payments. The amount of payment to research volunteers is guided by the National Institutes of Health policies. In general, patients are not paid for taking part in research studies at the National Institutes of Health.

4. Problems or Questions. If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Constantine A. Stratakis, M.D.; Building 10, Room 10N262, Telephone: 301-496-4686.

You may also call the Clinical Center Patient Representative at 301-496-2626.

5. Consent Document. Please keep a copy of this document in case you want to read it again.

COMPLETE APPROPRIATE ITEM(S) BELOW:			
A. Adult Patient's Consent I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study. _____ Signature of Adult Patient/Legal Representative Date		B. Parent's Permission for Minor Patient. I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby give permission for my child to take part in this study. (Attach NIH 2514-2, Minor's Assent, if applicable.) _____ Signature of Parent(s)/Guardian Date	
C. Child's Verbal Assent (If Applicable) The information in the above consent was described to my child and my child agrees to participate in the study. _____ Signature of Parent(s)/Guardian Date			
THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE FROM FEBRUARY 13, 2004 THROUGH FEBRUARY 13, 2005.			
_____ Signature of Investigator Date		_____ Signature of Witness Date	

PATIENT IDENTIFICATION

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY (Continuation Sheet)

• Adult Patient or • Parent, for Minor Patient

NIH-2514-1 (5-98)

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FAX TO: (301) 480-3126

File in Section 4: Protocol Consent